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中国食品药品国际交流中心
SERVIER
施维雅（天津）制药有限公司

CFDA Issued the *Opinions on Further Strengthening the Investigation and Handling of Food and Drug Illegal Cases*

To implement the decisions and deployments of the CPC Central Committee and the State Council on food and drug safety, implement the "Four Strictest" requirements, strengthen the supervision and administration of food and drug safety, severely punish food and drug violations and crimes, and effectively protect the people's food and drug safety, on August 15, 2017, CFDA issued the *Opinions on Further Strengthening the Investigation and Handling of Food and Drug Illegal Cases* (hereinafter referred to as the *Opinions*).

The *Opinions* clearly require food and drug regulatory authorities at all levels to resolutely implement the "Four Strictest" requirements, and earnestly fulfill the political responsibility of supervision; improve the case investigation system, establish work mechanisms for smooth investigation and handling of cases; intensify the case follow-ups and risk control of related product varieties; strengthen the evaluation and supervision of case handling to ensure effective case investigation and handling. We will adhere to the people-oriented and problem-oriented stance, consolidate responsibility and accountability, and effectively reinforce food and drug supervision and administration, intensify the case investigation and handling efforts, and severely punish food and drug illegal and criminal cases of sorts.

(August 22, 2017)

国家食品药品监督管理总局印发《关于进一步加强食品药品案件查办工作的意见》

为贯彻党中央、国务院关于食品药品安全工作的决策部署，落实“四个最严”要求，切实加强食品药品安全监管，严惩食品药品违法犯罪行为，有效保障人民群众饮食用药安全，2017年8月15日，国家食品药品监管总局印发《关于进一步加强食品药品案件查办工作的意见》（以下简称《意见》）。

《意见》明确要求，各级食品药品监管部门要坚决贯彻“四个最严”要求，切实履行监管政治责任；完善案件查办制度，建立顺畅查办工作机制；强化案件后续处理，加强涉案产品风险防控；强化案件督办考核，确保案件查办落到实处。要以对人民群众高度负责的态度，坚持问题导向，强化责任担当，切实加强食品药品监管，加大案件查办力度，严厉查处各类食品药品违法犯罪案件。（2017-08-22）

CFDA Issued in Conjunction with the Ministry of Finance the Reward Measures for Reporting Illegal Activities Concerning Food and Drug

To improve the reward system for case reporting, further mobilize the enthusiasm of the masses in this respect, and crack down on food and drug violations and crimes, recently, CFDA issued in conjunction with the Ministry of Finance the newly revised *Reward Measures for Reporting Illegal Activities Concerning Food and Drug* (hereinafter referred to as the *Measures*), which has come into force as of the date of promulgation. The Measures consist of a total of 28 Articles in 6 Chapters, including General Provisions, Reward Conditions, Reward Standards, Reward Procedures, Supervision & Administration, and Supplementary Provisions.

In addition, the Measures also refined the reward conditions and reward procedures, and authorized the provincial food and drug regulatory authorities and financial authorities to lay down specific provisions for reward decisions, review and approval, and reward grant procedures. (August 22, 2017)

国家食品药品监督管理总局会同财政部印发食品药品违法行为举报奖励办法

为完善举报奖励制度，进一步调动群众举报积极性，严厉打击食品药品违法犯罪行为，近日，国家食品药品监督管理总局会同财政部印发新修订的《食品药品违法行为举报奖励办法》（以下简称《办法》）。《办法》共六章二十八条，分总则、奖励条件、奖励标准、奖励程序、监督管理和附则， 自发布之日起施行。

此外，《办法》还细化了奖励条件，完善了奖励程序，并授权各省级食品药品监督管理部门、财政部门对奖励决定、审批、发放程序等作出具体规定。（2017-08-22）

Published by
China Center for Food and Drug International Exchange
Servier (Tianjin) Pharmaceutical Co., Ltd.

CFDA Issued the *Interpretations of Issues Related to Promulgated Reference Preparations*

On August 18, 2017, CFDA has issued the Interpretations of Issues Related to Promulgated Reference Preparations, which read as follows:

I. Reference preparations produced by an identical manufacturer with materials supplied by different licensees (limited to enterprises only in Europe, the United States and Japan) of the same parent company, can be regarded as equivalent.

II. Reference preparations produced by an identical manufacturer with materials supplied by different licensees of different parent companies, can be regarded as equivalent provided that appropriate evidence is furnished to validate the conformance of prescriptions, manufacturing processes and product quality of the products of different licensees.

III. Reference preparations marketed in the EU and with different places of origin, and with materials supplied by an identical licensee, can be regarded as equivalent provided that appropriate evidence is furnished to validate the conformance of prescriptions, manufacturing processes and product quality of the products of different places of origin; otherwise they cannot be, generally speaking, regarded as equivalent, and the place of origin in the list of reference preparations shall prevail.

IV. Since the controlled-release and prolonged-release preparations may have multiple reference preparations, the expert review conference for reference preparation selection will focus only on the enterprise's product filed for review, to determine its appropriateness as reference preparation; as well as its inappropriateness to be applied to another enterprise's products, if so, it shall be filed separately.

(August 18, 2017)

国家食品药品监督管理总局印发《已发布参比制剂有关事宜说明》

2017年8月18日，国家食品药品监督管理总局就已发布参比制剂有关事宜进行说明。内容如下：

一、同一总公司下的不同持证商（仅限欧美日企业）供应的，同一生产厂商生产的产品，可视为等同。

二、非同一总公司下的不同持证商供应的，同一生产厂商生产的产品，如能提供适宜证据证明不同持证商产品的处方、生产工艺和产品质量相同，可视为等同。

三、同一持证商供应的，欧盟上市不同产地的产品，如能提供适宜的证据证明不同产地产品的处方、生产工艺和产品质量相同，可视为等同；否则一般不可视为等同，以参比制剂目录中的产地为准。

四、由于缓释控释制剂可能存在多个参比制剂，故参比制剂遴选专家审评会仅针对企业已备案品种进行审评，确认备案的参比制剂能否作为参比制剂，该参比制剂未必适用于其他企业产品，如不适用可另行备案。

（2017-08-18）

CFDA Issued the *Notice on Promoting the Pilot Work of Drug Marketing Authorization Holder (MAH) System*

On August 21, 2017, CFDA issued the *Notice on Promoting the Pilot Work of Drug Marketing Authorization Holder (MAH) System* (Department of Drug and Cosmetics Supervision, CFDA [2017] No. 68) to provincial and municipal food and drug administrations of Beijing, Tianjin, Hebei, Shanghai, Jiangsu, Zhejiang, Fujian, Shandong, Guangdong, and Sichuan, to notify the relevant matters in the pilot work and require to:

I. Implement the legal responsibility of the holders.

II. Integrate technical resources to promote specialized large-scale production.

III. Grant the holders the permission of multi-site commissioned production.

IV. Allow the holders to sell drugs of their own volition or upon entrustment.

V. Accelerate the review & approval of the registration of product varieties related to the pilot enterprises.

VI. The holders shall perform the duty of pharmacovigilance and annual reports.

国家食品药品监督管理总局印发《关于推进药品上市许可持有人制度试点工作有关事项的通知》

2017年8月21日，国家食品药品监督管理总局就推进药品上市许可持有人制度试点工作向北京、天津、河北、上海、江苏、浙江、福建、山东、广东、四川省（市）食品药品监督管理局下发《关于推进药品上市许可持有人制度试点工作有关事项的通知》（食药监药化管〔2017〕68号）。通知要求：

一、落实持有人法律责任。

二、整合技术资源，促进专业化规模化生产。

三、允许持有人多点委托生产。

四、允许持有人自行或委托销售药品。

五、加快试点企业有关申报注册品种的审评审批。

六、持有人应开展药物警戒和年度报告。

七、试点区域内药品生产企业可参照试点内容管理。

VII. The management of drug manufacturers within the pilot areas may refer to the pilot work contents.
VIII. Improve drug regulatory responsibilities of regulatory authorities of two places.
IX. Actively explore the pilot models.
X. Sum up pilot experience on a timely basis. (August 15, 2017)

八、完善两地药品监管责任。
九、积极探索试点模式。
十、及时总结试点经验。
（2017-08-15）

CFDA Issued the Technical Guidelines on the Study of Pharmacokinetics/Pharmacodynamics of Antibacterial Drugs

To further regulate and guide the study of antibacterial drugs in China, CFDA has organized the formulation of the *Technical Guidelines on the Study of Pharmacokinetics/Pharmacodynamics of Antibacterial Drugs*, which shall be promulgated on August 21, 2017.

(August 4, 2017)

国家食品药品监督管理总局发布抗菌药物药代动力学/药效学研究技术指导原则

为进一步规范和指导我国抗菌药物研究，国家食品药品监督管理总局组织制定了《抗菌药物药代动力学/药效学研究技术指导原则》，于2017年8月21日 发布。

（2017-08-04）

Good Laboratory Practice Released

To ensure the quality of non-clinical drug safety evaluation, and guarantee the safety of public medication, on August 2, 2017, CFDA issued the newly revised *Good Laboratory Practice* (CFDA Order No. 34) (hereinafter referred to as the GLP).

With a total of 50 Articles in 12 Chapters, the *GLP* is comprised of General Provisions, Terms and Definitions, Organization and Personnel, Facilities, Apparatus & Equipment and Experimental Materials, Experimental Systems, Standard Operating Procedures, Implementation of Study, Quality Assurance, Data Files, Entrusting Party and Supplementary Provisions. The *GLP* will come into force as of September 1, 2017, whereupon the *Good Laboratory Practice* (CFDA Order No. 2) released on August 6, 2003 shall be repealed simultaneously. (August 2, 2017)

《药物非临床研究质量管理规范》发布

为保证药物非临床安全性评价研究的质量，保障公众用药安全，2017年8月2日，国家食品药品监督管理总局发布了新修订的《药物非临床研究质量管理规范》（国家食品药品监督管理总局令第34号）（以下简称《规范》）。

《规范》共12章50条，包括总则、术语及其定义、组织机构和人员、设施、仪器设备和实验材料、实验系统、标准操作规程、研究工作的实施、质量保证、资料档案、委托方和附则。《规范》将于2017年9月1日起施行，2003年8月6日发布的《药物非临床研究质量管理规范》（原国家食品药品监督管理局令第2号）同时废止。（2017-08-04）

CFDA Issued the *Self-inspection & Verification of Drug Clinical Trial Data for Registration Applications*

CFDA has decided to conduct clinical trial data verification for newly received drug registration applications of 61 drugs whose clinical trials have been completed and which are applying for production or import, and released the *Self-inspection & Verification of Drug Clinical Trial Data for Registration Applications* ([2017] No. 91) on August 2, 2017. The relevant matters are hereby announced as follows:

I. If the drug registration applicants found inauthenticity of clinical trial data before CFDA verification, they shall take the initiative to apply for withdrawal of registration application, and CFDA shall announce the list of withdrawals without affixing accountability.
II. Center for Food and Drug Inspection of

国家食品药品监督管理总局发布《关于药物临床试验数据自查核查注册申请情况的公告》

国家食品药品监督管理总局决定对新收到61个已完成临床试验申报生产或进口的药品注册申请进行临床试验数据核查。2017年8月2日，发布《关于药物临床试验数据自查核查注册申请情况的公告》（2017年第91号），将有关事宜公告如下：

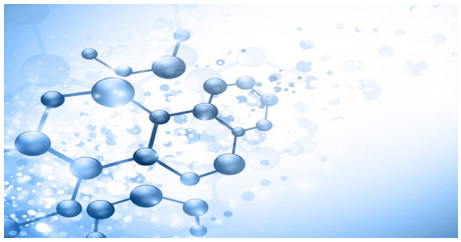
一、在国家食品药品监督管理总局组织核查前，药品注册申请人自查发现药物临床试验数据存在真实性问题的，应主动撤回注

CFDA shall publicize on its website the on-site verification plan, and inform the applicants of drug registration and the local competent provincial food and drug administrations; 10 working days after the public notification, the Center shall inform the date for on-site verification and no longer accept the applicants' withdrawal of drug registration applications.

III. CFDA shall severely punish the applicants, responsible persons and managers of drug clinical trials and responsible persons of CROs found with frauds in clinical trial data on-site verification, and shall hold responsible the inspectors of provincial food and drug administrations who failed to perform their duties.

Annex: List of Registration Applications for 61 Drugs Subject to Self-inspection & Verification of Clinical Trial Data (Omitted)

(August 2, 2017)



册申请，国家食品药品监督管理总局公布其名单，不追究其责任。

二、国家食品药品监督管理总局食品药品审核查验中心将在其网站公示现场核查计划，并告知药品注册申请人及其所在地省级食品药品监管部门，公示10个工作日后该中心将通知现场核查日期，不再接受药品注册申请人的撤回申请。

三、国家食品药品监督管理总局将对药物临床试验数据现场核查中发现数据造假的申请人、药物临床试验责任人和管理人、合同研究组织责任人从重处理，并追究未能有效履职的食品药品监管部门核查人员的责任。

附件：61个药物临床试验数据自查核查注册申请清单（略） （2017-08-02）

CFDA Issued the *Announcement on Cleanup Results of the Second Batch of Normative Documents*

According to the requirements of the *Implementation Outline of Constructing A Government Ruled by Law* (2015-2020) printed and issued by the CPC Central Committee and the State Council and with a view to better carrying out the "establishment, modification, abolishment and interpretation" of laws and regulations on food and drug supervision and administration and fully promoting the administration according to law, CFDA organized to clean up again relevant normative documents and decided to abolish and declare the second batch of normative documents invalid. The *CFDA's Directory of the Normative Documents (2nd Batch) Still Valid* and the *CFDA's Directory of the Normative Documents (2nd Batch) Announced as Abolished or Declared as Invalid* are hereby promulgated.

Annulment or declaration as invalid of such normative documents shall not tarnish the effectiveness of the past decisions made as based on these documents, unless otherwise explicitly stipulated.

(August 3, 2017)

国家食品药品监督管理总局发布《关于第二批规范性文件清理结果的公告》

根据中共中央、国务院印发的《法治政府建设实施纲要（2015—2020年）》的要求，为做好食品药品监管法律制度"立改废释"工作，全面推进依法行政，国家食品药品监督管理总局再次组织对相关规范性文件进行了清理，并决定废止和宣布失效第二批规范性文件。2017年7月31日，将《国家食品药品监督管理总局第二批继续有效的规范性文件目录》和《国家食品药品监督管理总局第二批废止和宣布失效的规范性文件目录》予以公布。

对上述予以废止或者宣布失效的规范性文件，除另有明确规定外，均不涉及过去根据这些文件所作出处理决定的效力。

（2017-08-03）

Medical Devices

CFDA Issued the Guidelines for Technical Review of Dental Implant Equipment Registration

To strengthen the supervision and guidance of the registration of medical devices, and further improve the quality of registration review, CFDA has organized to formulate the *Guidelines for Technical Review of Dental Implant Equipment Registration*, which shall be issued on August 9, 2017.

(August 9, 2017)

医疗器械

国家食品药品监督管理总局发布牙科种植机注册技术审查指导原则

为加强医疗器械产品注册工作的监督和指导，进一步提高注册审查质量，国家食品药品监督管理总局组织制定了《牙科种植机注册技术审查指导原则》，于2017年8月9日发布。 （2017-08-09）

General Information

A Quick Look of the Overall Reform Process of the Review & Approval System for Drugs and Medical Devices

7/22/2015

China Food and Drug Administration (CFDA) issued the *Announcement on Conducting Self-inspection & Verification of Drug Clinical Trial Data*; therewith, "the most stringent" inspection in history of clinical trial data of drugs was fully launched.

8/9/2015

The State Council issued the *Opinions on the Reform of the Review & Approval System for Drugs and Medical Devices*, which holds that: before the end of 2016, the backlog of registration applications shall be eliminated; in 2018, application review and approval in strict compliance with the prescribed timelines shall be achieved, and a more scientific and efficient review & approval system shall be established.

11/11/2015

CFDA released the *Announcement on Policies Pertaining to the Review & Approval of Drug Registration*, which defines provisions for 10 items including: improving the review & approval criteria for generic drugs; optimizing the review & approval of clinical trial applications; implementing centralized review of the similar drugs; strict review of the safety and efficacy of drugs; accelerating the review & approval of drugs urgently needed in clinical settings; and severe punishment of the frauds in clinical trial data, to promote drug review & approval reform by adopting the rigid-flexible combined management pattern.

12/17/2015

The State Council approved the establishment of an Inter-Ministerial Joint Conference System for the Reform of the Review & Approval System for Drugs & Medical Devices, comprising 10 Ministries and Commissions: CFDA, State Commission Office for Public Sector Reform, National Development and Reform Commission, Ministry of Science and Technology, Ministry of Industry and Information Technology, Ministry of Finance, Ministry of Human Resources and Social Security, National Health and Family Planning Commission, State Administration of Traditional Chinese Medicine, and Health Department of PLA General Logistics Department, to form a synergy with mutual support.

2/6/2016

The General Office of the State Council issued the *Opinions on Carrying out Consistency Evaluation of the Quality and Efficacy of Generic Drugs*, which clarified the objects and time limits for such consistency evaluations; determined the selection criteria of the reference preparations; reasonably selected the evaluation methods; and laid down the subject responsibility of the enterprises. The regulatory authorities are required to strengthen the management of consistency evaluation and encourage enterprises to conduct consistency evaluation.

2/26/2016

CFDA issued the *Opinions on Implementing Priority Review & Approval to Eliminate the Backlog of Drug Registration Applications*, which clarified the scope, procedures and work requirements for priority review & approval.

综合信息

一表速览药品医疗器械审评审批制度改革全过程

2015年7月22日

国家食品药品监督管理总局发布《关于开展药物临床试验数据自宜核查工作的公告》，"史上最严"药物临床试验数据检查全面启动。

2015年8月9日

国务院印发《关于改革药品医疗器械审评审批制度的意见》。意见提出，2016年底前消化注册申请积压存量，2018年实现按规定时限审批，建立更科学、高效的审评审批体系。

2015年11月11日

《国家食品药品监督管理总局关于药品注册审评审批若干政策的公告》发布。公告对提高仿制药审批标准、优化临床试验申请的审评审批、实行同品种集中审评、严格审查药品的安全性和有效性、加快临床急需等药品的审批、严惩临床试验数据造假行为等10项内容进行了规定，刚柔并济推进药审改革。

2015年12月17日

国务院批复同意建立药品医疗器械审评审批制度改革部际联席会议制度，联席会议由食品药品监管总局、中央编办、发展改革委、科技部、工业和信息化部、财政部、人力资源和社会保障部、卫生计生委、中医药局、总后勤部卫生部等10个部门和单位组成。各部委相互支持，形成工作合力。

2016年2月6日

国务院办公厅发布《关于开展仿制药质量和疗效一致性评价的意见》。意见明确了开展仿制药质量和疗效一致性评价对象和时限，确定参比制剂遴选原则，合理选用评价方法，落实企业主体责任，要求监管部门加强对一致性评价工作的管理，鼓励企业开展一致性评价工作。

2016年2月26日

《总局关于解决药品注册申请积压实行优先审评审批的意见》出台。意见明确了优先审评审批的范围、程序和工作要求。

5/26/2016

The General Office of the State Council promulgated the *Notice on the Issuance of Pilot Plan on Drug Marketing Authorization Holder System* to perform pilot work in 10 provinces (municipalities): Beijing, Tianjin, Hebei, Shanghai, Jiangsu, Zhejiang, Fujian, Shandong, Guangdong and Sichuan. This initiative is conducive to active innovation of new drugs in drug R&D institutions and by scientific researchers; to optimization of industrial restructuring and resource allocation; to promotion of professional division of labor; to improving industrial concentration and avoiding duplication of investment and construction; it is therefore of great significance to encouraging drug innovation, and enhancing the quality of drugs.

2016年5月26日

国务院办公厅发布《关于印发药品上市许可持有人制度试点方案的通知》，在北京、天津、河北、上海、江苏、浙江、福建、山东、广东、四川等10个省（市）开展药品上市许可持有人制度试点。该举措有利于药品研发机构和科研人员积极创制新药，有利于产业结构调整和资源优化配置，促进专业分工，提高产业集中度，避免重复投资和建设，对于鼓励药品创新、提升药品质量具有重要意义。

8/10/2016

CFDA issued the *Announcement on Issues Pertaining to Associated Review & Approval of Pharmaceutical Packaging Materials and Pharmaceutical Excipients with Drugs*, to change the separate review & approval of packing materials, containers and pharmaceutical excipients in immediate contact with drugs into associate review & approval during the review and approval of drug registration application.

2016年8月10日

《总局关于药包材药用辅料与药品关联审评审批有关事项的公告》发布，将直接接触药品的包装材料和容器、药用辅料由单独审批改为在审批药品注册申请时一并审评审批。

10/26/2016

CFDA issued the *Priority Review and Approval Procedure for Medical Devices*, the scope of which covers medical devices with significant clinical advantages for the diagnosis or treatment of rare diseases, malignant tumors; medical devices for diagnosis or treatment of the elderly-specific, frequently-occurring diseases with no effective diagnostic or therapeutic means currently; medical devices with significant clinical advantages dedicated to children; medical devices urgently needed in clinical settings and without similar products approved for registration in China; as well as medical devices included in the National Science And Technology Major Projects or National Key R&D Plans.

2016年10月26日

总局发布《医疗器械优先审批程序》，实施优先审批的医疗器械范围为诊断或治疗罕见病、恶性肿瘤且具有明显临床优势的医疗器械，诊断或治疗老年人特有和多发疾病且目前尚无有效诊断或治疗手段的医疗器械，专用于儿童且具有明显临床优势的医疗器械，临床急需且在我国尚无同品种产品获准注册的医疗器械，以及列入国家科技重大专项或国家重点研发计划的医疗器械。

3/9/2017

CFDA issued the *Announcement on Issuing the Provisions for Expert Consultation Committee on Drug Registration Review (Interim)* to improve the review quality control system and give full play to the experts' important roles in formulating technical guidelines for R&D of drugs, technical standards, and participation in drug registration review decision-making.

2017年3月9日

总局发布《关于发布药品注册审评专家咨询委员会管理办法（试行）的公告》，该办法旨在健全审评质量控制体系，充分发挥专家在制定药物研发技术指导原则、技术标准以及参与药品注册审评决策中的重要作用。

4/5/2017

CFDA released the *Decision on Adjusting Certain Procedures for Administrative Review and Approval of Drugs*. Since May 1, 2017, the decisions on administrative review and approval procedures for drug clinical trials, drug supplementary applications, and imported drug re-registration shall be made by Center for Drug Reevaluation, CFDA on behalf of CFDA.

2017年4月5日

《国家食品药品监督管理总局关于调整部分药品行政审批事项审批程序的决定》发布。自2017年5月1日起，药物临床试验、药品补充申请、进口药品再注册行政审批事项审批程序，调整为由国家食品药品监督管理总局药品审评中心以国家食品药品监督管理总局名义作出。

4/6/2017

CFDA promulgated the Decision on Adjusting Certain Procedures for Administrative Review and Approval of Medical Devices, to adjust the review and approval procedures for clinical trials, re-registration, registration renewal, registration of change, for which CFDA is responsible.

2017年4月6日

《国家食品药品监督管理总局关于调整部分医疗器械行政审批事项审批程序的决定》发布，对总局负责的临床试验审批事项、再注册和延续注册审批事项、注册变更审批事项等医疗器械行政审批事项的审批程序进行调整。

5/11-12/2017

CFDA issued consecutive Announcements to solicit public comments on the *Relevant Policies on Accelerating the Review and Approval of New Pharmaceuticals and Medical Devices for Marketing to Encourage the Innovation of Pharmaceuticals and Medical Devices (Draft for Comments)* and other 3 Drafts for Comments, involving a package of policies of accelerating the review & approval of new pharmaceuticals & medical devices, reform of clinical trial management, implementation of whole life cycle management of pharmaceuticals and medical devices, and protection of the rights and interests of innovators.

6/19/2017

CFDA becomes a full member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This marks that China's drug supervision and administration has embarked upon the world arena as an important member for developing international drug standards.

7/19/2017

The Central Leading Group for Comprehensively Deepening Reforms deliberated and adopted the *Opinions on Deepening the Reform of the Review and Approval System to Encourage the Innovation of Drugs and Medical Devices* in the 37th Meeting. The Meeting pointed out that, the quality, safety, innovation and development of drugs and medical devices constitute an important guarantee for building a Healthy China. We will reform and improve the review and approval system; stimulate the vitality for innovation and development of the pharmaceutical industry; reform the clinical trial management; accelerate review and approval for marketing; promote generic drug quality and efficacy consistency evaluation; improve the food and drug regulatory system to urge enterprises to enhance innovation and R&D capabilities; and speed up the marketing of new drugs and effective medicines, to meet the urgent need for clinical medication.

(July 24, 2017)

2017年5月11日~12日

总局连续发布公告，就《关于鼓励药品医疗器械创新加快新药医疗器械上市审评审批的相关政策（征求意见稿）》等4个征求意见稿公开征求意见，其中涉及加快创新药械上市审评审批、改革临床试验管理、实施药品医疗器械全生命周期管理、保护创新者权益等一揽子新政策。

2017年6月19日

国家食品药品监督管理总局成为国际人用药品注册技术协调会（ICH）正式成员。这标志着中国药品监管从此登上世界舞台，成为国际药品标准制订的重要一员。

2017年7月19日

中央全面深化改革领导小组第三十七次会议审议通过了《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》。会议指出，药品医疗器械质量安全和创新发展是建设健康中国的重要保障。要改革完善审评审批制度，激发医药产业创新发展活力，改革临床试验管理，加快上市审评审批，推进仿制药质量和疗效一致性评价，完善食品药品监管体制，推动企业提高创新和研发能力，加快新药好药上市，满足临床用药急需。

(2017-07-24)

The Supreme People's Court and the Supreme People's Procuratorate Issued Judicial Interpretations for Severe Punishment of Frauds Manifested in Application Dossiers for Registration of Drugs and Medical Devices

With a view to punishing, as per the law, the frauds manifested in application dossiers for registration of drugs and medical devices, and safeguarding the life and health rights and interests of the people, recently, the Supreme People's Court and the Supreme People's Procuratorate promulgated the *Interpretations on Several Issues Concerning the Application of Law in Handling the Criminal Cases of Frauds Manifested in Application Dossiers for Registration of Drugs and Medical Devices*, which has entered into force as of September 1, 2017.

The *Interpretations* clarify that, where false drug non-clinical study report, drug clinical trial report and related dossiers, or medical device clinical trial report and related dossiers are deliberately provided by the institutions for non-clinical study of drugs, drug and medical device clinical trial institutions, contract research organizations and their staff, the latter (provider) shall be convicted and punished in accordance with the provisions of Article 229 of the Criminal Law: "deliberate provision of false proof documents". The specific circumstances constituting a crime of documents fraud are also clarified.

The *Interpretations* provide that, where the staff of the drug registration applicant

最高人民法院最高人民检察院发布司法解释严惩药品、医疗器械注册申请材料造假行为

为依法惩治药品、医疗器械注册申请材料造假的犯罪行为，维护人民群众生命健康权益，日前，最高人民法院、最高人民检察院公布《关于办理药品、医疗器械注册申请材料造假刑事案件适用法律若干问题的解释》，自2017年9月1日起施行。

《解释》明确，药物非临床研究机构、药物和医疗器械临床试验机构、合同研究组织及其工作人员，故意提供虚假的药物非临床研究报告、药物临床试验报告及相关材料或者医疗器械临床试验报告及相关材料的，按照刑法第二百二十九条规定的"故意提供虚假证明文件"定罪处罚，并明确了材料造假构成犯罪的具体情形。

《解释》规定，药品注册申请单位的工

deliberately use the false drug non-clinical study report, drug clinical trial report and related dossiers, whereupon the production and sale of drugs are made via drug approval documents based upon frauds, they shall be convicted and punished in accordance with the crime of manufacturing and selling counterfeit drugs. Where the staff of the drug registration applicant instruct their counterparts in the institutions for non-clinical study of drugs, the drug clinical trial institutions, and the contract research organizations to provide false drug non-clinical study report, drug clinical trial report and related dossiers, they shall be convicted and punished as joint crime of providing false proof documents. Where the staff of drug registration applicants and staff of the institutions for non-clinical study of drugs, drug clinical trial institutions, and contract research organizations jointly commit document frauds, whereupon the production and sale of drugs are made via drug approval documents based upon frauds, committing concurrently the crime of providing false proof documents and the crime of producing and selling counterfeit drugs, they shall be convicted and punished where the provisions with heavier penalties shall prevail.

The promulgation of the *Interpretations* shall have a strong deterrent effect to violators in frauds of application dossiers for registration of drugs and medical devices; it is therefore of great significance to further regulating the R&D and protecting the safety of drugs and medical devices, and effectively safeguarding the people's life and health rights and interests.

(August 14, 2017)

作人员故意使用虚假药物非临床研究报告、药物临床试验报告及相关材料，骗取药品批准证明文件生产、销售药品的，以生产、销售假药罪定罪处罚。药品注册申请单位的工作人员指使药物非临床研究机构、药物临床试验机构、合同研究组织的工作人员提供虚假药物非临床研究报告、药物临床试验报告及相关材料的，以提供虚假证明文件罪的共同犯罪论处。药品注册申请单位的工作人员和药物非临床研究机构、药物临床试验机构、合同研究组织的工作人员共同实施材料造假行为，骗取药品批准证明文件生产、销售药品，同时构成提供虚假证明文件罪和生产、销售假药罪的，依照处罚较重的规定定罪处罚。

《解释》的出台，将有力地震慑药品、医疗器械注册申请材料造假违法犯罪分子，对进一步规范药品、医疗器械研制行为，保障药品、医疗器械安全，切实维护人民群众的生命健康权益，具有重要意义。

(2017-08-14)

Notes: • All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.
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